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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/509,239	03/23/00	BRUCK	C B45110

020462 HM22/1116  
SMITHKLINE BEECHAM CORPORATION  
709 SWEDELAND ROAD P O BOX 1539  
KING OF PRUSSIA PA 19406-0939

EXAMINER	
WINKLER, U	
ART UNIT	PAPER NUMBER

1648  
DATE MAILED: 11/16/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/509,239

Applicant(s)

BRUCK ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 32-77 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: Seq comply

Art Unit: 1648

### **DETAILED ACTION**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Art Unit: 1648

Group I, claims 32, 35, 37-40 and 43-53, as the claims read on Tat linked to a fusion partner, drawn to a vaccine composition.

Group II, claim 32, 36- 40 and 43-53, as the claims read on Nef linked to a fusion partner, drawn to a vaccine composition.

Group III, claim 32, 33-54 as the claims read on Nef linked to Tat or Nef linked to Tat linked to a fusion partner, drawn to a vaccine composition.

Group IV claims 55-57, drawn to a nucleic acid and a host cell containing nucleic acid.

Group V, claims 58, 60, 62, 64, 65, 67, 68, 70, 72 and 74, drawn to a method of producing a fusion protein.

Group VI, claims 59, 61, 63, 66, 69, 71 and 73, drawn to a method of producing a recombinant protein.

Group VII, claims 76 and 77, drawn to a vaccine comprising a recombinant Tat containing protein.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VII appears to be the vaccine composition comprising an HIV-Tat protein or derivative thereof and a fusion partner. Schluesener (J. Neurolosci. Res. 1996) discloses a Tat derivative fusion protein vaccine. Therefore, the technical feature linking the inventions of groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Art Unit: 1648

The special technical feature of group I is considered to be a vaccine composition comprising an HIV Tat fusion protein.

The special technical feature of group II is considered to be a vaccine composition comprising an HIV Nef fusion protein.

The special technical feature of group III is considered to be a vaccine composition comprising an HIV Nef - HIV Tat fusion protein or an HIV Nef -HIV Tat-fusion partner fusion protein.

The special technical feature of group IV is considered to be a nucleic acid encoding an HIV-Tat fusion protein linked to HIV-Nef in either the Nef-Tat or Tat-Nef orientation.

The special technical feature of group V is considered to be a method of producing a fusion protein comprising an HIV-Tat fusion protein linked to HIV-Nef in either the Nef-Tat or Tat-Nef orientation.

The special technical feature of group V is considered to be a method of producing recombinant HIV Nef-protein or derivative thereof or and HIV Tat protein or derivative thereof.

The special technical feature of group VI is considered to be a vaccine composition comprising a recombinant Tat containing protein.

Groups I-IV and VII are compositions and are distinct from groups V and VI which are drawn to methods. Groups I-IV and VI are compositions and each is distinct from the other because they contain different materials. Group I comprises a vaccine composition that contains an HIV Tat fusion protein, which is distinct from the vaccine composition of the HIV Nef fusion protein of Group II. Group III is distinct from groups I and II in that it contains a combination of HIV Nef and HIV Tat as a fusion protein or additional attached to another fusion partner. The

Art Unit: 1648

search for one group would not be coextensive with the search for the other group. Group IV comprises the DNA sequence for the vaccine proteins of group III; and DNA is made up of nucleic acids. Group VII comprises a vaccine composition that contains HIV Tat but is not necessarily a fusion protein. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group, therefore, restriction for examination purposes is proper.

Groups V and VI are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Groups V is drawn to a method of producing a recombinant fusion protein. Groups VI is drawn to a method of producing a recombinant protein. Though there may be overlap between these two methods in question, each utilizes different staring materials and therefore the outcome is expected to be different.

Accordingly, groups I-V are not so linked by the same or corresponding technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

Art Unit: 1648

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.

  
JEFFREY STUCKER  
PRIMARY EXAMINER